

Applicant: Peavey, Todd
Application Serial No.: 10/634,475
Filing Date: August 4, 2003
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Remarks/Arguments:

Introduction

Claims 42-54 are pending in this application and stand rejected.

Section 103 Rejections

The Examiner has rejected Claims 42-54 under 35 U.S.C. 103 (a) as being obvious over U.S. Patent No. 4,108,174 to Slivenko. In addition, the Examiner has rejected Claims 53, 54 under 35 U.S.C. 103 (a) as being obvious over Slivenko in view of U.S. Patent 5,989,223 to Chu. Applicants respectfully traverses.

Claims 42-54 are rejected under 35 U.S.C. §103 (a) as being anticipated by U.S. Patent 4,108,174 (Slivenko). Amongst other things, the Examiner contends that Slivenko discloses a catheter interlock system that includes an extractable engagement member (catheter 65a) and a subcutaneously implanted port member (19). The Examiner contends that it is inherent that the engagement member being a catheter has a gripping member and tactile indicia to facilitate gripping and torquing at the proximal end in the form of a turn knob. The Examiner further states that Slivenko discloses inserting the device within a living body (column 7, line 25), inserting the engagement member within the device (which the Examiner contends is “inherently percutaneous”), and rotating the engagement member.

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With respect to independent claim 42, the Examiner contends that Slivenko meets the claimed limitations but fails to include the engagement member having a tapered protrusion. Having acknowledged the deficiency of Slivenko, the Examiner then concludes that at the time of the invention, it would have been obvious to construct the tubular body (catheter 65) of Slivenko with tapered protrusions instead of flutes 75 and 77. The Examiner considers the substitution of flutes 75 and 77 with tapered protrusions to be a mere reversal of essential working parts of a device and relies on *In Re Gazda*, 219 Fd. 2d 1449 (CCPA 1955) for support that such reversal is only routine skill in the art. These rejections are traversed for the following reasons.

At the outset it is pointed out that while, as recognized by the Examiner, the Slivenko device is inserted within a living body, insertion of the engagement member within the device is not inherently percutaneous as the Examiner contends. In fact, the Slivenko device is constructed and inserted in a living body with a portion of the device housing extending upward beyond the surface of the skin. See column 6, lines 54-59, wherein it is stated that the length of the housing 19 is sufficient to extend from a blood vessel in which the conduit 15 is inserted to a point "outside the living body, i.e., outside the skin layer". In column 8, lines 60-63, it is then stated that a "suitable plug (not shown) may be applied the end of the cap 55 to keep the interior clean until next use". It is accordingly clear the device in Slivenko is not described to be, nor

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does it teach or suggest, percutaneous entry of a catheter or other engagement member, such as a needle, into the access device.

Independent claim 42 is clear that the extractable engagement member is “for percutaneous patient entry” which is not taught or suggested by Slivenko. Consistent with the claimed extractable engagement member for percutaneous patient entry, the distal end of the tubular body is defined as including a “tapered protrusion”. Independent claim 42 is likewise directed to an extractable engagement member for establishing “percutaneous” vascular access to a patient. Claim 42 similarly recites that the distal end of the tubular body has a “tapered protrusion”. The “tapered protrusion”, as described in the specification of the subject application facilitates easy insertion and removal of the engagement member, which structure is advantageous in a percutaneous entry system, such as that described and claimed in the present invention.

In the Slivenko device, flutes 75 and 77 are defined as being in the outer walls of the catheter tip. The Examiner contends that it is merely a reversal of the essential working parts to reverse this structure and place flutes in the interior of the cannula receptacle and provide protruding guides 79 and 80 on the catheter outerwall. Initially, there is absolutely nothing in Slivenko to suggest such a reversal of flutes/guides as indicated by the Examiner. Next, even if it were routine, *arguendo*, as contended by the Examiner to make such a structural reversal, such

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structural modification would still fail to meet the invention as claimed. The flutes 75, 77 as well as the guides 79, 80 in Slivenko are clearly not shown as being tapered as claimed. Indeed, they appear to be of constant width and length. Nor is there any reason one skilled in the art would even consider tapering the flutes or guides in Slivenko inasmuch as the catheter is neither intended nor designed to be percutaneously inserted. Accordingly, the outer surface of the Slivenko cannula is not a factor for purposes of access to the device as would be the claimed engagement member, which is for percutaneous entry.

Lastly, the Examiner also recognizes that the catheter flutes 75 and 77 engage protruding guides 79 and 80 that are on the interior of the cannula receptacle 43 which is affixed within a counterbore in rotatable valve body 23. The Examiner recognizes that if the Slivenko catheter outer wall were provided with tapered protrusions, one could eliminate the need for the cannula receptacle 43, thereby increasing device simplicity. It is submitted that this is a pure application of hindsight of the claimed invention to the Slivenko device. As noted hereinabove, there is nothing in Slivenko that suggests placing tapered protrusions on the outer catheter wall since the Slivenko catheter, unlike the claimed engagement member, is not configured for percutaneous entry. Furthermore, the removal of the Slivenko cannula receptacle 43 in a manner suggested by the inventor to increase simplicity, would render the Slivenko device inoperable for other purposes. As stated in column 4, lines 21 et seq., a pair of rods 51 and 53 are inserted in the cylindrical openings formed by the opposing grooves between the receptacle 43 and the grooves

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in the counterbore of the valve body 23. Such rods form an interlock in the opposing grooves as a "safety" feature in the event the epoxy holding the cannula receptacle to the valve body should for any reason let loose. The rods, thus, assure unison rotative movement between the cannula receptacle and the valve body whenever rotative force is applied to the cannula receptacle.

Accordingly, if the cannula receptacle were to be removed as suggested by the Examiner, the safety feature as described by Slivenko would be eliminated thereby changing the structural characteristics of the Slivenko device in a manner not contemplated. Accordingly, for these various reasons, Claims 42-54 are patentable over Slivenko. Allowance of claims 42-54 is respectively requested.

Claims 53, 54 are rejected under 35 U.S.C. 103 (a) as being obvious over Slivenko in view of U.S. Patent 5,989,223 to Chu. The Examiner contends that Claims 53, 54 differ from Slivenko in calling for the gripping member to include a turn Knob with indicia on it. The Examiner further contends that Chu teaches a valve having a knob with gripping members and indicia describing the condition of the valve, and therefore it would have been obvious to modify the device of Slivenko to include a knob with indicia as taught by Chu. These rejections are respectfully traversed for the following reasons.

Dependent claims 53, 54 are all dependent claims depending ultimately from patentable independent claim 42 and thereby including all its limitations. Even though the Examiner has

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not pointed out anything in Chu that would suggest the specific limitations recited in claims 253, 54 since independent claim 42 distinguishes patentably over Chu, dependent claims 53, 54 are likewise distinguishable.

Having responded fully to the outstanding Office Action, it is believed that the application is now in condition for allowance. An early Notice of Allowance is accordingly earnestly sought.

Should the Examiner wish to discuss this application in further detail, the Examiner is invited to contact Applicant's undersigned attorney by telephone at (973) 331-1700.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Stephen Cannavale", written over a horizontal line.

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